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IS 14944 (2001): Surgical Dressings - Methods of Test [MHD
14: Hospital Planning]



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“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक
शल्य चिकित्सा मरहम पट्टियाँ — परीक्षण पद्धतियाँ

Indian Standard
SURGICAL DRESSINGS — METHODS OF TEST

ICS 11.160

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Surgical Dressings Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

Protective coverings for wounds are called dressings. These are placed directly on to wounds and may be used to control bleeding, to absorb secretions or to prevent contamination by bacteria or foreign material such as dirt.

Dressings should be large enough to cover a wound completely. They should be sterile so that they do not introduce bacteria that could cause infection. A dressing should also be absorbent in order to prevent accumulation of sweat, otherwise the skin around the wound becomes moist and soft, thus encouraging infection. These are of various types, for example, adhesive bandages, which consist of absorbent pads held in place. They are commonly used to protect small wounds. Non stick dressings consist of a non-adherent layer of perforated polyethylene or viscose with an impregnated gauze pad backing. Improvised dressings which are used in an emergency almost any clean dry, and absorbent materials may be used to cover wound.

In view of the fact that a large number of surgical dressings are used in the country by the doctors as well as consumers, the committee decided to formulate a standard covering methods of test for various types of surgical dressings. The standard covers test methods for both adhesive and non-adhesive types of dressings. The standard gives provision for conducting various tests for minimum breaking load, elasticity, extensibility, adhesiveness, water-vapour permeability, waterproofness, absorbency, content of antiseptics, etc.

There is no ISO/IEC standard on the subject. This standard has been prepared based on the information provided/ data provided in the British Pharmacopoeia.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the results of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding of numerical values (*revised*)'. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

SURGICAL DRESSINGS — METHODS OF TEST

1 SCOPE

1.1 This standard specifies the methods of test for various types of surgical dressings.

2 REFERENCES

2.1 The following Indian Standards are necessary adjuncts to this standard:

<i>IS No.</i>	<i>Title</i>
3073 : 1967	Assessment of surface roughness
3689 : 1966	Conversion factors and conversion tables for yarn counts

3 STANDARD TEST ATMOSPHERE

3.1 Unless specified otherwise, the standard test atmosphere shall be a temperature of $27 \pm 2^\circ\text{C}$ and a relative humidity of 65 ± 5 percent.

4 CONDITIONING FOR TESTING

4.1 The materials to be tested for weights, areas, threads per stated length, minimum breaking load and absorbency are unwrapped, opened out or unwound and subjected to standard test atmosphere (*see* 3.1) for not less than 24 hours immediately before testing unless specified otherwise, and shall be tested in the same atmosphere.

5 QUALITY OF REAGENTS

5.1 Unless specified otherwise, pure chemicals and distilled or deionized water shall be employed in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

6 TESTS METHODS

6.1 Fibre Identification

6.1.1 Cotton

- a) When examined under microscope, each fibre shall be seen to consist of a single cell, up to about 4 cm long and up to 40 μm wide, in the form of a flattened tube with thick and rounded walls and often twisted.
- b) Treat with iodinated zinc chloride solution. The fibres shall become violet.
- c) The fibres shall be soluble in sulphuric acid (66 percent). They shall swell uniformly and except for the contents of the lumen, finally dissolve in ammoniacal copper oxide

solution. They shall be insoluble in 1.25 M sodium hydroxide.

- d) To 0.1 g, add 10 ml of zinc chloride solution, heat to 40°C and allow to stand for 2.5 h, shaking occasionally. The fibres shall not dissolve.

6.1.2 Polyacrylonitrile

- a) When examined under a microscope, the fibres shall be seen to be twisted ribbons of uniform width and thickness or cylinders of uniform width. In cross-section, the former are reniform or dumb-bell shaped and the latter are approximately circular.
- b) When examined under a microscope, the fibres shall be clearly visible in water or liquid paraffin but not easily visible in cedarwood oil or a liquid of similar refractive index.
- c) The fibres shall dissolve in dimethyl-formamide at 90 to 95°C within 5 min. They shall be insoluble in ammoniacal copper oxide solution, in cold acetone and in boiling xylene.

6.1.3 Polyamide 6

- a) Heat 50 mg with 0.5 ml of 7 M hydrochloric acid in a sealed glass tube at 110°C for 18 h and allow to stand for several hours. No crystals shall be produced.
- b) To 50 mg, add 10 ml of 7 M hydrochloric acid. The material shall disintegrate in the cold and dissolve completely within a few minutes.
- c) The material shall dissolve in a 70 percent (*m/m*) solution of anhydrous formic acid.

6.1.4 Polyamide 6/6

- a) In contact with a flame, the material shall melt and burn, forming a hard globule of residue and shall give off a characteristic odour resembling that of celery.
- b) Place 50 mg in an ignition tube held in the vertical position and heat gently until thick fumes are evolved; when the fumes fill the tube, withdraw it from the flame and insert a strip of nitrobenzaldehyde paper. A violet-brown colour shall be produced slowly on the paper and fade slowly in air; it shall disappear immediately on washing with 1 M sulphuric acid.

- c) To 50 mg, add 10 ml of 7 M hydrochloric acid. The material shall disintegrate in the cold and dissolve within a few minutes.
- d) The material shall not dissolve in an 80 percent (m/m) solution of anhydrous formic acid.

6.1.5 Polyester

- a) When heated in dimethylformamide and in 1, 2 -dichlorobenzene, the fibre shall dissolve with difficulty.
- b) To 50 mg, add 10 ml of 7 M hydrochloric acid. The fibre shall remain intact even after prolonged immersion.

6.1.6 Rubber

Treat carefully a few small pieces with a little carbon tetrachloride in an evaporating dish, allow to swell, add 0.2 ml of bromine, allow to stand for 2 min, add 1 g of phenol and remove the carbon tetrachloride by heating on a water-bath. The pieces shall be stained blue to violet-red.

6.1.7 Viscose

When the term viscose is used in tests for fibre identification, it means bright viscose or matt viscose as appropriate.

6.1.7.1 Bright viscose

- a) When examined in dry state under a microscope, the fibres shall be seen to be of a uniform width with many longitudinal parallel lines distributed unequally over the width. In waddings, the end-cuts are more or less straight. In cross-section, they are approximately circular or elliptical, with a diameter of about 10 to 20 µm; the surface of the fibre shall be seen to be uneven or crenated.
- b) When examined under a microscope, the fibres shall be clearly visible in chloral hydrate solution and in lactophenol, almost invisible in cresol and invisible when viewed between crossed polars in the orthogonal position.
- c) Treat with iodinated zinc chloride solution. The fibres shall become violet.
- d) Dissolve the residue obtained in the test for sulphated ash (*see* 6.1.8) in 5 ml of sulphuric acid with slight warming, allow to cool and add carefully 0.2 ml of hydrogen peroxide solution (10 vol). The solution shall not become orange-yellow.
- e) Soak in iodine solution for a few minutes, remove the excess of reagent with filter paper and add 0.05 ml to 0.1 ml of sulphuric acid

(66 percent). The fibres shall be stained blue.

- f) Treat with a 1.0 percent (m/v) solution of phloroglucinol in ethanol (90 percent) followed by hydrochloric acid. The fibres shall not be coloured red.
- g) The fibres shall be soluble in sulphuric acid (66 percent). They shall swell and finally dissolve in ammoniacal copper oxide solution. They shall be insoluble in formic acid and almost insoluble in 1.25 M sodium hydroxide.
- h) To 0.1 g, add 10 ml of zinc chloride solution, heat to 40°C and allow to stand for 2.5 hours, shaking occasionally. The fibres shall dissolve completely.

6.1.7.2 Matt viscose

Comply with the tests for identification described in 6.1.7.1 with the following modifications.

- a) and b) When examined under a microscope, the fibres shall be seen to contain numerous granular particles with average diameters of 0.25 to 1 µm.
- d) The solution shall become orange-yellow after the addition of the hydrogen peroxide solution.
- h) The granular particles shall remain undissolved.

6.1.8 Wood Pulp

- a) When examined under a microscope, the fibres shall show the characteristics of the timber, usually coniferous, from which the wood pulp has been prepared, as follows:

Coniferous woods

Detached tacheids, transparent and laterally distended; bordered pits indistinct and may appear as rounded, somewhat jagged holes; distinct lattice-like striations may be present; fibre ends are broadly rounded and swollen.

Broad-leaved woods

Generally similar to coniferous woods but vessels show numerous well-preserved pits; wall thickness tends to be uneven and may be pierced by slit-like pores.

- b) The fibres shall swell and finally dissolve in ammoniacal copper oxide solution, some developing spherical swellings.
- c) Soak in iodine solution for a few minutes, remove the excess of reagent with filter paper and add 0.05 ml to 0.1 ml of sulphuric acid (66 percent). The fibres shall be stained blue.

6.1.9 Wool

- a) When examined under a microscope, each hair shall be seen to be composed of a cuticle of imbricated, flattened, epithelial scales and a wide cortex of nucleated spindle shaped fibres and may have a narrow medulla of polyhedral or rounded cells. The free projecting edges of the epithelial scales are directed towards the apex of the hair and give rise to numerous irregular transverse markings on the surface of the hair.
- b) The hairs shall be insoluble in sulphuric acid (66 percent) at 20°C; soluble in 1.25 M sodium hydroxide at 100°C; insoluble in but coloured blue by ammoniacal copper oxide solution.
- c) Treat with trinitrophenol solution. The hairs shall be stained yellow.

6.2 Yarn Numbers

Yarn are normally numbered in the Tex system. The tex number is the weight, in g, of 1 000 m of yarn. Agreed rounded values and their equivalents in traditional counts and numbering systems are given in IS 3689.

The sectional count of rubber threads is given by the value of its cross-sectional area, expressed in square millimetres, multiplied by 1 000.

NOTE — The sectional count corresponds to the tex count for a nominal density of 1 Mg/m³ (= 1 g/cm³). The use of the sectional count is recommended.

6.3 Threads per Stated Length

6.3.1 Unstretched

Method I

Determine the number of threads over a distance of 10 cm, or if this is impracticable, over the greatest distance allowed by the material being examined. If the size or number of units available permits, repeat the determination at not less than four independent positions selected as being representative of the material being examined and calculate the average number of threads per 10 cm, unless otherwise specified in the standard.

Method II

Determine the number of threads over a distance of 2.5 cm by means of a suitable instrument. If the size or number of units available permits, repeat the determination at not less than four independent positions selected as being representative of the material being examined and calculate the average number of threads per 10 cm, unless otherwise specified in the standard.

Method III

Determine the total number of warp threads in the unstitched material and measure the width from the outside of the last warp thread on one side to the outside of the last warp thread on the opposite side. If the number of units permits, repeat the determination on not less than four other units selected as being representative of the material being examined and calculate the average number of threads per 10 cm, unless otherwise specified in the standard.

Method IV

Determine the numbers of warp threads and weft threads in an area of 10 cm × 10 cm in each of three places. Calculate the average number of threads per 10 cm in the warp and in the weft directions.

If the width of the ribbon gauze is less than 10 cm, count the number of threads over the whole of the width and calculate the number of threads per 10 cm on the basis of the declared width. If the width of the ribbon gauze is greater than 10 cm, omit the selvage in the count.

6.3.2 Fully Stretched

Determine the number of warp threads while the material is fully stretched by the application of a force of 10 N per cm width (about 1.07 kgf per cm width) in the weft direction. Determine the number of weft threads while the material is fully stretched by application of a force 10 N per cm width (about 1.07 kgf per cm width) in the warp direction. Count the number of threads in a length of 10 cm, except that if there are 10 or more threads per cm, make the count in a length of 2.5 cm using a suitable instrument. If it is impracticable to measure over a length of 10 cm, use the greatest distance allowed by the material being examined. If the size or number of units available permits, repeat the determination at not less than four other independent positions selected as being representative of the material being examined and calculate the average number of threads per 10 cm, unless otherwise specified in the standard.

6.4 Weight per Unit Area

6.4.1 Non-Adhesive Dressings

Method I

Determine the weight of the material being examined (*W* g). Measure its unstretched width (*a* cm) and its fully stretched length (*b* cm) (see 6.6). Calculate the weight per unit area, in g m⁻² from the expression 10 000 *W*/*ab*.

Method II

Determine the weight of the material being examined

(W g). Measure its unstretched width (a cm) and its unstretched length (b cm). Calculate the weight per unit area, in g m^{-2} from the expression $10\,000\, W/ab$.

Method III

Cut a convenient sample from the material being examined, preferably not less than 100 cm^2 in area, and determine its weight (W g) and its area ($A\text{ cm}^2$). If the test has been carried out on a dried sample, correct the weight for percentage moisture regain. Calculate the weight per unit area, in g m^{-2} , from the expression $10\,000\, W/A$.

If the size or number of units of the material being examined permits, repeat the determination on further samples and calculate the average value.

Method IV

Determine the weight of the whole ribbon gauze and calculate its area by multiplying the nominal width by the length, measured on the unrolled gauze under slight tension along the centre. Calculate the weight per unit area, in g m^{-2} .

6.4.2 Adhesive Dressings

Method I

Determine the weight of the material being examined (W g). Measure its width and length and calculate its total area ($A\text{ m}^2$). Cut out rectangular full-width samples, each weighing 3 to 4 g, from three positions approximately equidistant along the length of the material being examined, combine the samples and weigh accurately (w g). Macerate the combined samples with successive 250-ml quantities of chloroform or other suitable solvent until the adhesive mass appears to have been removed, decant each extract through a sieve with a nominal mesh aperture of $106\text{ }\mu\text{m}$ and return any fibres retained by the sieve to the bulk of the fabric.

Cover the extracted fabric with a 50 percent (v/v) solution of acetic acid and allow to stand until all of the zinc oxide retained in the fabric has dissolved. Decant the liquid and wash the fabric with successive quantities of water until the washings are free from acidity, passing the washings through the sieve, and return any fibres retained by the sieve to the bulk of the fabric.

Dry the extracted fabric at 105°C , recondition it by subjecting it to the standard test atmosphere for 24 h and determine its weight (f g).

Calculate the weight per unit area, in g m^{-2} , from the expression fW/Aw .

Method II

Determine the weight of the whole sample (W g).

Measure its unstretched width and its fully-stretched length (see 6.6) and calculate its total area ($A\text{ m}^2$). Complete the test described under Method I, beginning at the words 'Cut out rectangular.....'.

Method III

Measure the area of a sample weighing 9.0 to 11.0 g. Macerate the sample in successive portions of petroleum spirit (boiling range, 40 to 60°C) or other suitable solvent until the adhesive appears to have been completely removed and dry the residual material to constant weight in a current of warm air. From the area of the unextracted sample, calculate the weight per unit area of backing material, in g m^{-2} .

6.4.3 Weight of Adhesive Mass

Carry out the procedure described under 6.4.2 Method I, Method II or Method III, as prescribed in the specification. Calculate the weight of adhesive mass, in g m^{-2} , from the expression $(w - f)W/Aw$ for Methods I and II or $(W - f)/A$ for Method III where W is the original weight (in g) of unextracted sample, f is the weight (in g) of dry residual backing material and A is the original area (in m^2) of unextracted sample.

If the spread area of the adhesive ($B\text{ m}^2$) is different from the original area of the sample, substitute B for A in the above expression.

6.5 Minimum Breaking Load

Method I

Prepare five strips of the material being examined as representative of the material as possible, each 200 mm in length and of known widths not greater than 25 mm (or cut longitudinally to give strips of that width) so that both surfaces are freely accessible to the standard test atmosphere for 24 h preceding the test. Determine the breaking load of each strip in turn on a machine having a movable grip with a constant rate of traverse of 270 to 330 mm per minute and a capacity such that when the sample breaks, the reading obtained is 15 to 85 percent of the full-scale deflection. Place one end of the strip in the fixed grip and the other in the movable grip in such a way that the distance between the grips is 100 mm. Any strip that slips during the test or breaks within 10 mm of the grips should be excluded and replaced by another strip. Repeat the procedure on the other four strips and calculate the average value.

Method II

Carry out Method I, using six representative strips, each 200 mm long, and a machine having a movable grip with a constant rate of traverse of 90 to 110 mm per minute. Place one end of a strip in the fixed grip and the other in the movable grip in such a manner that the distance between the grips is 175 mm except

that in the case of plastic films, the distance may be reduced to 100 mm. Repeat the procedure on the other five strips and calculate the average value.

Method III

For ribbon gauzes more than 50 mm wide, make two cuts parallel to the selvedge edges so as to obtain from the centre of the ribbon pieces at least 60 mm wide. Remove warp threads from the two sides so as to leave fringes about 5 mm long and obtain a width of the remaining warp threads of exactly 50 mm.

For ribbon gauzes of 50 mm or less wide, test the sample using the full width and calculate the result with respect to a 50 mm width. Prepare five pieces of ribbon gauze of sufficient length to allow the distance between the clamps of the machine to be 200 mm. Clamp each piece in turn between the jaws of a machine with a constant rate of traverse of 90 to 110 mm per minute and determine the breaking load. Calculate the average value.

Method IV

Prepare 10 pieces, each 50 mm wide and of sufficient length to allow the distance between the clamps of the machine to be 200 mm. Cut five pieces in the weft direction and five in the warp direction, not less than 15 mm from the edges avoiding folded or fraying edges. Clamp each piece in turn between the jaws of a machine with a constant rate of traverse of 90 to 110 mm per minute and measure the breaking load of each piece. Calculate the average value.

6.6 Elasticity

Method I

Measure the length of the material in the unstretched condition (L cm). Place one end of the material in a fixed grip and the other in a movable grip of a spring dynamometer or other suitable device in such a way that the material stretches in the elastic direction. Ensure that the ends of the material are securely held, for example, by means of pins in the grips, to minimize any slip while the material is under tension. Mark the material between the grips at points approximately 50 cm apart (l cm). Apply gradually to the movable grip, a force of 10 N per cm width (about 1.0 kgf per cm width) ensuring that the full load is applied within 5 s from starting to stretch. Measure the length of the material between the marks, to the nearest cm, as soon as the full load is applied (s cm).

Maintain the load for a total stretching time of 55 to 65 s, ensuring that at no time the load is exceeded, and then release the tension as rapidly as possible without allowing the material to tangle. Remove the material from the grips, loosely fold the whole length

in a zig-zag with folds of 15 to 20 cm and allow the material to relax for 4.75 to 5.25 min from the time of release of the tension. In the case of adhesive material, fold it edge-to-edge along its length with the adhesive surface innermost before removing the material from the grips. Unfold the zig-zag and measure the length of material between the marks to the nearest cm (r cm).

Calculate the fully stretched length (Ls/l) and the regain length (Lr/l).

Repeat the procedure on another sample and calculate the average values.

Method II

For tubular products that are elastic in the width direction, cut a sample 10 cm long and mark two measuring points across the width, the distance between which is not less than 50 percent of the nominal lay-flat width. Apply a load of 20 N (about 2 kgf) by means of fingers or stirrups inserted in the tube.

6.7 Extensibility

Method I

Carry out the tests on a machine with a constant rate of traverse using six samples of the material being examined, each at least 100 mm long and as representative as possible of the material, and calculate the average result.

Determine the load required to produce a 20 percent extension at a rate of extension of 270 to 330 mm per minute. The load shall not be more than 14 N per cm width (about 1.4 kgf per cm width).

Maintain the 20 percent extension of the material for 55 to 65 s, allow to recover for 4.75 to 5.25 min and redetermine the length. The permanent set of the elongated material shall not be more than 5 percent of the original unstretched length.

Method II

Measure the width of a 10-cm length of stockinette in the unstretched condition. Insert two circular fingers, one fixed and one movable, within the stockinette in such a way that they are parallel to each other and to the length of the sample. By means of a spring dynamometer or other suitable device, apply a load of 2.5 kg within 5 s to the movable finger. Measure the extended width of the stockinette.

6.8 Adhesiveness

The tape shall comply with Tests 1 and 2 given in 6.8.2 and 6.8.3.

6.8.1 Apparatus

6.8.1.1 Stainless steel plate

Use a plate of corrosion-resistant steel containing less than 0.12 percent of carbon, not less than 8 percent of nickel and not less than 17 percent of chromium, with sides 200 mm × 50 mm and thickness about 2 mm, of Brinell hardness between 130 and 200. The surface of the plate is mechanically polished and then abraded in a direction parallel with the longer side of the plate with a suitable abrasive. The abraded surface is examined by making five transverse measurements within an area bounded by two lines 10 mm from the longer axis of the plate to ensure that the gritting has produced a surface roughness (*see* IS 3073) that corresponds to an arithmetical deviation from the mean line of the profile of 0.05 to 0.40 µm, a maximum height of irregularities of less than 4 µm, a sampling length of 0.8 mm and a traversing length of five times the sampling length.

The plate is marked along its longer sides at intervals of 30 mm, the first mark being 25 mm from one of the shorter sides.

Between each test, keep the plate under conditions that prevent accidental scratching liable to change the state of the surface.

Before use, clean the steel plate with absorbent cotton moistened with toluene, suspend the plate in a toluene vapour-bath in such a manner that the plate is not in contact with the liquid toluene, allow the vapour line to reach the top of the plate and maintain the plate in this position for 5 min. Remove the plate from the vapour-bath and condition it for about 30 min in the standard test atmosphere.

6.8.1.2 Roller

Use a polished metal cylinder not less than 50 mm in diameter. Increase the weight, if necessary, by adding weights so as to apply a load of 20 N (2 kgf) per cm width of the material being examined.

6.8.2 Test 1

Condition the roll or sheet of tape for 24 hours before the test. For tapes in the form of strips, unwind from the roll at a speed of approximately 30 cm/s immediately before testing and cut off a piece about 60 mm long. If the material being examined is not more than 25 mm wide, use the whole width; if it is more than 25 mm wide, carry out the test on strips 25 mm wide cut from the material. For tapes in the form of sheets, remove the protective covering immediately before testing and cut a piece of the tape of appropriate dimensions. Take care not to contaminate the adhesive surface during the test.

Bring the adhesive side of one end of the prepared strip into contact with the cleaned surface of the stainless steel plate in such a manner that the whole width of the strip is attached to the plate for a distance of 25 mm from one end, with the sides of the strip parallel to the longer sides of the plate, and the unattached portion of the strip overhanging the end of the plate.

When attaching the strip, ensure that no air bubbles are trapped between the strip and the plate. Apply pressure to the attached portion of the strip by means of the roller, making four passages along the length of the strip at a speed of about 60 cm/min, and allow to stand in the standard test atmosphere for 10 min. Mark on the plate, the line of the end of the strip. Attach a weight equivalent to 0.8 N (80 gf)/cm width of the strip to the free end of the strip by means of a stirrup so that the load is evenly distributed across the width of the strip. Suspend the plate in a hot-air oven fitted with a device for circulating air at 36 to 38°C for 30 min, in such a manner that the plate is inclined at an angle of 2° from the vertical in a direction that prevents the strip peeling from the plate and the weight is hanging freely. Repeat the procedure on further four strips.

The top edge of the strip attached to the plate shall not slip by more than 2.5 mm during the period in the oven.

For adhesive tapes and plastic film that are very extensible, attach a piece of non-extensible adhesive tape of the same width to the strip before applying the load.

For adhesive tapes and textile fabric that are extensible in the direction of the length, carry out the test with the elastic thread running across the width of the plate and the load applied in the direction of the non-extensible threads. In these circumstances, the test can be performed only on materials at least 25 mm wide. If the material being examined is exactly 25 mm wide, attach a length of non-extensible adhesive tape (about 60 mm long and of the same width as the length of the strip) squarely to the strip so that the unattached portion of the tape overhangs the end of the plate and attach the stirrup bearing the weight to the free end of the tape so that the load is evenly distributed.

6.8.3 Test 2

Condition the roll or sheet of tape for 24 hours immediately preceding the test. For tapes in the form of strips, unwind from the roll at a speed of approximately 30 cm/s immediately before testing and cut off a piece about 400 mm long. If the material being examined is not more than 25 mm wide, carry out the test on strips 25 mm wide, cut from the

material. For tapes in the form of sheets, remove the protective covering immediately before testing and cut a piece of the tape of appropriate dimensions. Take care not to contaminate the adhesive surface during the test.

Apply the strip to the centre of the cleaned surface of the stainless steel plate so that the sides of the strip lie parallel to the longer sides of the plate. Apply pressure to the attached portion of the strip by means of the roller, making four passages along the length of the strip at a speed of about 60 cm/min, and allow to stand in the standard test atmosphere for 10 min.

Determine the force required (when applied at an angle of 180° at a constant rate of traverse of 270 to 330 mm/min) to detach the strip from the plate using a suitable instrument such that the force required represents 15 to 85 percent of the full-scale deflection. Detach the strip, observing the force being applied as the first 25-mm and then each succeeding 30-mm length is detached. Calculate the average of these six observations. Repeat the procedure on further four strips and calculate the average of the five mean values.

The average force required shall not be less than 1 N (100 gf)/cm width.

6.9 Water-Vapour Permeability

6.9.1 Tapes

If the tape is declared to be permeable to water vapour, its permeability shall be not less than 500 g m^{-2} per 24 h when tested by the following procedure.

6.9.1.1 Apparatus

A box constructed of suitable non-corrodible material, having external dimensions of about $95 \text{ mm} \times 25 \text{ mm} \times 20 \text{ mm}$, weighing not more than 60 g when empty, and completely closed except for a rectangular opening, $80 \text{ mm} \times 10 \text{ mm}$, at the top. The box is completely impermeable to water and to water vapour, other than the opening (which is covered with the material being examined).

6.9.1.2 Method

Place a tray containing approximately 1 kg of anhydrous calcium chloride on the floor of an electrically-heated humidity cabinet fitted with an efficient means of circulating the air and maintained at 36 to 38°C . Place about 2 g of absorbent cotton in each of five boxes complying with the above specification. Pour about 20 ml of water into each and cover the opening in the top of each box with a strip of the material being examined, pressed down without stretching the material so that the opening is completely sealed. Ensure that the wet absorbent cotton is not in contact with the under surface of the material

being examined. The width of the material must be at least 5 mm greater than the corresponding dimension of the aperture.

Weigh the sealed boxes to the nearest mg and place them in the cabinet for about 18 h (noting the time to the nearest 15 min). Remove the boxes from the cabinet, allow to cool in the standard test atmosphere for 1 h and reweigh to the nearest mg.

From the mean loss in weight and the area of the opening in the top of each box, calculate the water vapour permeability in g m^{-2} per 24 h.

Calculate the result of the test as the average of the values found on the five samples.

6.9.2 Foam Dressings

6.9.2.1 Apparatus

A cylindrical chamber with separate lid constructed of suitable non-corrodible material, having external dimensions as shown in Fig. 1 and completely closed except for a circular opening, 40 mm in diameter, at the top. The separate lid has a central hole of the same diameter. It is attached to the chamber by means of four separate retaining bolts. A flat silicone rubber gasket, 2.4 to 2.6 mm in thickness, with a central circular opening, 54 to 56 mm in diameter, is inserted between the lid and the chamber. The chamber is completely impermeable to water and to water vapour, other than the opening (which is covered with the material being examined).

6.9.2.2 Method

Pour about 20 ml of water into each of five chambers complying with the above specification. Place a circular disc, 54 to 56 mm in diameter, of the material being examined on to the centre of the top surface of the chamber, locate the rubber gasket around it and clamp the lid in place using the four retaining bolts.

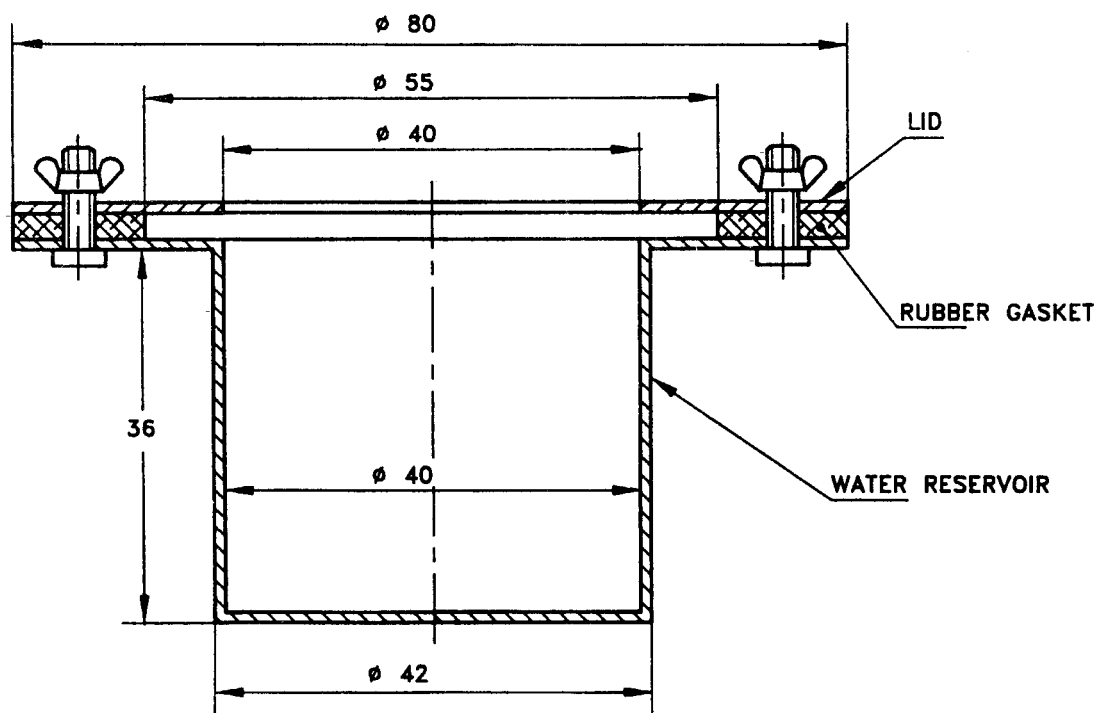
Place a tray containing approximately 1 kg of self-indicating silica gel, spread in a layer approximately 3 cm in depth, on the floor of an electrically heated cabinet fitted with an efficient means of circulating the air and maintained at 36 to 38°C .

Weigh the sealed chambers to the nearest mg and place them in the cabinet for 24 h. Remove the chambers from the cabinet, allow to cool in the standard test atmosphere for 1 h and reweigh to the nearest mg.

From the mean loss in weight and the area of the exposed surface of foam dressing, calculate the water vapour permeability in g m^{-2} per 24 h.

6.10 Waterproofness

No water shall pass through at least five of the specimens when tested by the following procedure.



All dimensions in millimetres.

FIG. 1 APPARATUS FOR THE DETERMINATION OF WATER VAPOUR PERMEABILITY

6.10.1 Apparatus

A suitable apparatus (see Fig. 2) consists of a cell that allows the application of hydrostatic head of 500 mm of water to a circular area of about 20 cm² of the non-adhesive side of the material being examined. The sample is held in a horizontal position by two rings, the lower one forming part of the cell. The ring surfaces in contact with the sample are covered by a suitable coating material, such as, rubber. A screw device allows clamps to be tightened so as to prevent leakage of water or the movement of the sample during the test. The hydrostatic head is generated by means of a vertical tube, of internal diameter about 10 mm, connected to the base of the cell.

6.10.2 Method

Prepare the samples without folding and without excessive handling. Fill the cell completely with water at 19 to 21°C. Place the sample which should be circular, with the largest diameter possible up to 5 cm, on the lower ring by sliding it horizontally in such a way as to avoid the inclusion of air between the surface of the water and the lower surface of the sample. Cover the upper surface with a dry filter paper, 45 mm in diameter, locate the upper ring and tighten the screw device. Pour water into the tube until the required level above the surface of the sample is

reached. Maintain the hydrostatic head for 5 min unless otherwise specified in the standard and examine the filter paper.

Repeat the procedure on further five samples.

6.11 Absorbency

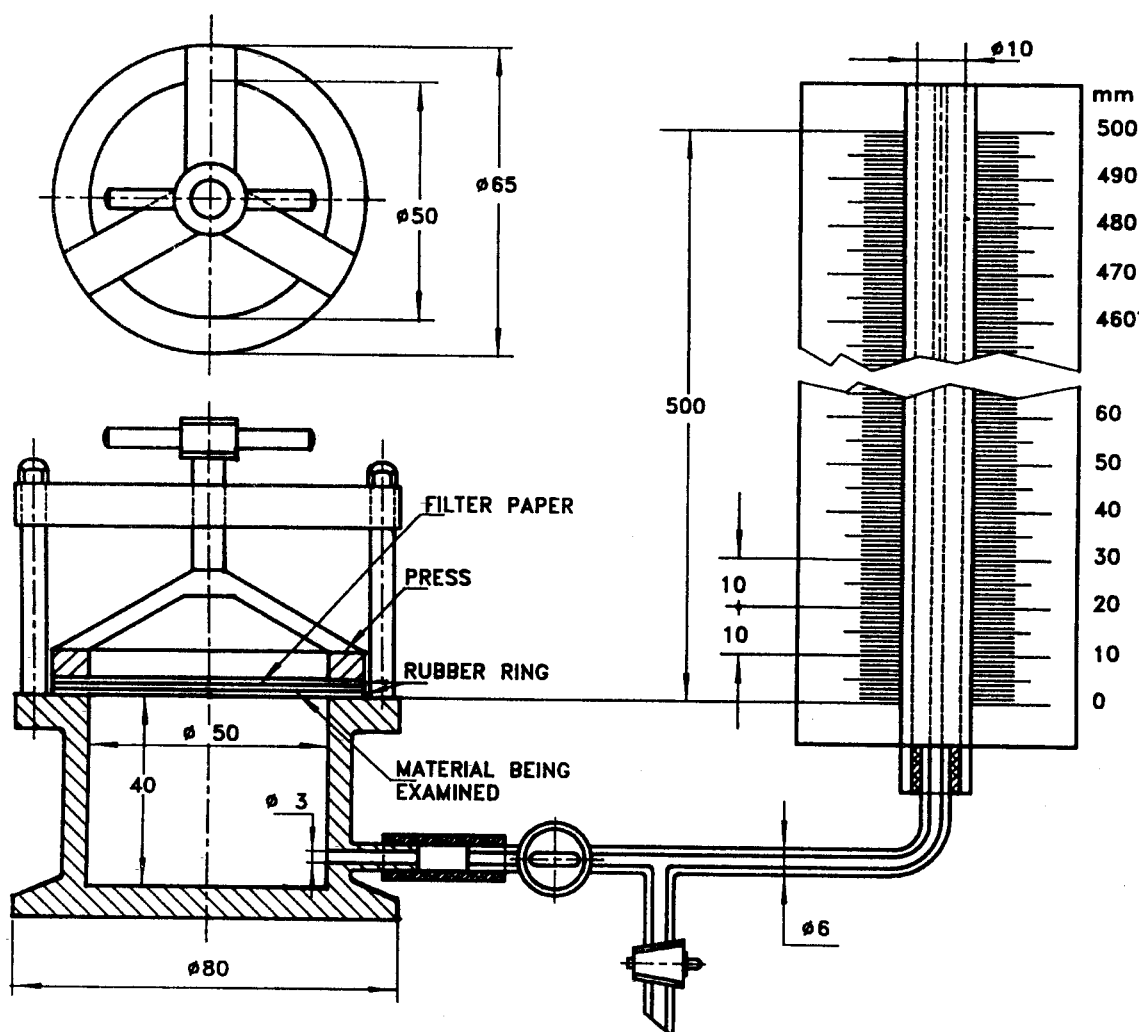
6.11.1 Apparatus

A dry, cylindrical copper wire basket, 80 mm high and 50 mm in diameter, fabricated from wire of diameter 0.4 mm and having a mesh aperture of 15 to 20 mm; the basket shall weigh 2.4 to 3.0 g.

6.11.2 Sinking Time

Method I

Weigh the basket to the nearest 10 mg. Take five samples, each of approximately 1 g, from different places in the material being examined, pack loosely in the basket and weigh the packed basket to the nearest 10 mg. Hold the basket with its long axis in the horizontal position and drop it from a height of about 10 mm into water at 20°C contained in a beaker at least 12 cm in diameter and filled to a depth of 10 cm. Measure with a stopwatch, the time taken by the basket to sink below the surface of the water. Repeat the procedure on two further samples and calculate the average value.



All dimensions in millimetres.

FIG. 2 APPARATUS FOR MEASUREMENT OF WATERPROOFNESS

Method II

Using forceps, fold a sample of the material, weighing 1 g, four times (that is, into 16-ply) and smooth the surface. For narrow ribbon gauze, fold as many times as is necessary to obtain a length not greater than 8 cm. Allow the material to drop lightly on to the surface of water at 20°C contained in a beaker at least 12 cm in diameter and filled to a depth of 10 cm. Measure with a stopwatch, the time taken for the sample to sink below the surface of the water. Repeat the procedure on two further samples and calculate the average value.

6.11.3 Water Holding Capacity

After the sinking time has been recorded in Test (a), Method I, remove the basket from water, allow it to drain for 30 s with its long axis in the horizontal position, transfer it to a tared beaker and weigh to the nearest 10 mg. Calculate the weight of water retained by the sample. Repeat the procedure on two further

samples and calculate the average value.

6.12 Water Soluble Substances

Use Method I, unless specified otherwise in the standard.

Method I

Boil 7 g with 700 ml of water for 30 min, stirring frequently, and replace the water lost by evaporation. Decant the liquid into a beaker, squeeze the residual liquid from the material carefully with a glass rod, mix the liquids and filter the extract whilst hot. Evaporate 400 ml and dry the residue to constant weight at 100 to 105°C.

Method II

Dry 5 g to constant weight at 105°C and determine the loss of weight. Heat slowly with 400 ml of water and boil for 1 min, cool by adding about the same

quantity of water and decant the liquid through a sieve with a nominal mesh aperture of 106 μm , wringing the material by hand to remove as much of the liquid as possible; return the material to the vessel and repeat the washing process with five 400-ml quantities of water. Place the washed material and any loose threads or fibres from the sieve in a beaker, cover with a 0.5 percent solution of diastase and maintain at 70°C, or if the material being examined contains wool, 45 to 50°C, until free from starch. Decant the liquid through the sieve, return any loose fibres or threads retained on the sieve to the bulk material in the vessel, repeat the washing process with boiling water and again return any loose fibres or threads retained on the sieve to the bulk material. Dry the material and determine the loss in weight.

For cotton crepe, cotton stretch, cotton and rubber elastic, heavy cotton and rubber elastic and elastic net bandages, and unbleached calico that has not been dyed, subtract from the loss in weight, 3 percent of the weight of the final dry sample; if the materials have been dyed, subtract 1 percent; for crepe bandage and domette bandage, subtract 2 percent.

Calculate the percentage of water soluble substances with reference to the material dried to constant weight at 105°C.

6.13 Ether Soluble Substances

Extract 5 g with ether in a Soxhlet apparatus for 4 h, operating the apparatus in such a manner that the rate is at least four extractions per hour. Evaporate the ether extract and dry the residue to constant weight at 100 to 105°C, unless specified otherwise in the standard.

6.14 Colour Fastness

Make two 8-ply pads, 5 cm $\times$ 5 cm, of the material being examined, place each pad between two pieces of standard undyed bleached cotton lawn and, for each set, sew the three pieces of material together along one edge to form a composite pad. Carry out Test A and Test B given below.

Test A

Saturate one of the composite pads with ethanol (70 percent), lay it smoothly in a suitable flat-bottomed dish, add sufficient ethanol (70 percent) to cover the pad completely, place a smooth, square glass plate, with sides of 5 cm and weighing about 50 g, centrally on top of the pad, press lightly on the glass plate to remove air bubbles and allow to stand at 36 to 38°C for 15 min. Without removing the glass plate, pour off the ethanol and allow the pad to stand at 36 to 38°C for 4 h. Remove the glass plate, separate the three pieces of cloth forming the composite pad, allow them to dry separately at a temperature not exceeding

60°C and examine the two outer pieces of undyed cloth for staining. They shall be virtually unstained.

Test B

Subject the other composite pad to steam at 134 to 138°C for 3 min in an autoclave together with a separate piece of the standard undyed bleached cotton lawn. Separate the three pieces of cloth forming the composite pad and compare the two outer pieces of cloth with the separate piece of undyed cloth. The pieces from the composite pad shall not be significantly different in colour from the separate piece.

6.15 Content of Antiseptics

6.15.1 Aminacrine Hydrochloride

Extract 25 g of the impregnated pad, in small pieces, with ether in an apparatus for the continuous extraction of drugs, (see Appendix XI F of BP, Edition 1988, Vol II), until the extraction of fatty matter is complete; shake the ether extract with 20 ml of water, allow to separate and reserve the lower aqueous layer. Dry the extracted material in a current of warm air and extract it again with methanol containing 1 ml of 2 M hydrochloric acid until extraction of the antiseptic is complete, evaporate the extract to about 10 ml on a water bath, add the reserved aqueous layer from the ether-extraction, followed by 100 ml of water, boil to reduce the volume to about 60 ml, cool and adjust the pH to 5.0 with a 10 percent (m/v) solution of sodium acetate. Add, with stirring, 5 ml of 0.04 M potassium hexacyanoferrate(III), allow to stand for 30 min, filter and wash the residue with 50 ml of water. To the combined filtrate and washings, add successively, mixing after each addition, 1 ml of hydrochloric acid, 1 g of sodium chloride, 5 ml of a 2.0 percent (m/v) solution of potassium iodide and 2 ml of a 15.0 percent (m/v) solution of zinc sulphate. Allow to stand for 3 min and titrate with 0.04 M sodium thiosulphate *VS* using a 1 percent (m/v) solution of sodium starch glycollate as indicator. Repeat the operation without the material being examined. The difference between the titrations represents the amount of sodium thiosulphate required. Each ml of 0.04 M sodium thiosulphate *VS* is equivalent to 0.029 85 g of $\text{C}_{13}\text{H}_{10}\text{N}_2\cdot\text{HCl}\cdot\text{H}_2\text{O}$.

6.15.2 Benzalkonium Chloride

6.15.2.1 Sample preparation

Determine the moisture content. Weight about 1.5 g of the medicated pad removed from adhesive dressing in duplicate in 250 ml beaker. Add 100 ml of distilled water and boil it vigorously. Decant the solution to another 250 ml beaker. Repeat the extraction of lint with 75 ml water and evaporation of decanted solution till the lint is free from benzalkonium chloride. [Follow

identification test B for benzalkonium chloride specified in British Pharmacopoeia, 1988 Ed, Vol I (p. 64) using 2 ml of solution]. Evaporate the decanted solution to about 50 ml and cool it. Transfer the above solution quantitatively to a separating funnel, washing the beaker with distilled water. Add 25 ml of chloroform, 10 ml of 0.01 N sodium hydroxide and 10 ml of freshly prepared 0.5 percent (*m/v*) solution of potassium iodide. Shake well and allow to separate. Discard the chloroform layer. Repeat the extraction with 10 ml of chloroform three times and discard the chloroform layer. Collect the aqueous layer in 500 ml iodine flask, add 40 ml of concentrated hydrochloric acid and allow to cool. Titrate with 0.005 M potassium iodate until deep brown colour is almost discharged. Add 2 ml chloroform and continue the titration. Shake vigorously until the chloroform layer no longer changes colour.

6.15.2.2 Blank preparation

Carry out blank titration on a mixture of 10 ml of freshly prepared 0.5 percent potassium iodide solution, 20 ml water and 40 ml hydrochloric acid.

6.15.2.3 Calculation

Benzalkonium chloride (%) =

$$\frac{(\text{Blank} - \text{Test result}) \times \text{Molarity of potassium iodate} \times 0.0354 \times 100}{\text{Weight of the sample on dry basis in g} \times 0.05}$$

6.15.3 Cetrimide

6.15.3.1 Sample preparation

Weight about 1.5 g of sample in duplicate in 250 ml beaker by removing the medicated pads from adhesive dressings. Add 100 ml of distilled water and boil it vigorously. Decant the solution to another 250 ml beaker. Repeat the extraction of lint with 75 ml water and evaporation of decanted solution till the lint is free from cetrimide [Follow identification test B of strong cetrimide solution given in British Pharmacopoeia, 1988 Ed, Vol I (p. 112)]. Evaporate the decanted solution to 50 ml and cool it. Transfer 100 ml of solution to a separating funnel. Add chloroform, 10 ml of 0.01 N sodium hydroxide and 10 ml of freshly prepared 0.5 percent (*m/v*) solution of potassium iodide. Shake well and allow to separate. Discard the chloroform layer. Repeat the washings with three times and discard the washings. Collect the aqueous layer in 500 ml iodine flask, add 40 ml of concentrated hydrochloride acid and allow to cool. Titrate with 0.005 M potassium iodide until deep brown colour is almost discharged. Add 2 ml chloroform and continue the titration. Shake vigorously, until the chloroform layer no longer

changes colour.

6.15.3.2 Blank preparation

Carry out blank titration on a mixture of 10 ml of freshly prepared potassium iodide solution, 20 ml water and 40 ml hydrochloric acid.

6.15.3.3 Calculation

$$\text{Cetrimide (\%)} = \frac{(\text{Blank} - \text{Test result}) \times \text{Molarity of potassium iodate} \times 3.364 \times 100}{\text{Weight of the sample in g} \times 0.05}$$

6.15.4 Chlorhexidine Hydrochloride

To 30 g of the impregnated pad, add 140 ml of water and 60 ml of 1 M hydrochloric acid, shake for 30 min and decant the extract. Shake the residue for 15 min with two 100-ml quantities of a mixture of 7 volumes of water and 3 volumes of 1 M hydrochloric acid, decanting each extract. Dilute the combined extracts to 1 000 ml with water. To 40 ml of this solution, add 45 ml of water and 5 ml of a 20 percent (*m/v*) solution of cetrimide, make just alkaline to litmus paper with 5 M sodium hydroxide, add 2 ml of a 1.0 percent (*v/v*) solution of bromine in 10 M sodium hydroxide and shake. Add 1 ml of propan-2-ol to suppress the froth, dilute to 100 ml with water and allow to stand at 18 to 22°C for 25 min. Measure the absorbance of the resulting solution at the maximum at 480 nm (see Appendix II B of British Pharmacopoeia, Ed 1988, Vol II). Calculate the content of $\text{C}_{22}\text{H}_{30}\text{Cl}_2\text{N}_{10} \cdot 2\text{HCl}$ using a calibration curve prepared from the absorbances obtained by repeating the operation using solutions containing 0.001 percent to 0.005 percent (*m/v*) of chlorhexidine hydrochloride in a mixture of 5 volumes of 1 M hydrochloric acid and 95 volumes of water and beginning at the words 'To 40 ml of this solution, add'.

6.15.5 Chlorhexidine Gluconate

Carry out the procedure described above under chlorhexidine hydrochloride but using solutions of chlorhexidine gluconate to prepare the calibration curve. Calculate the content of $\text{C}_{22}\text{H}_{30}\text{Cl}_2\text{N}_{10} \cdot 2\text{C}_6\text{H}_{12}\text{O}_7$.

6.15.6 Domiphen Bromide

Use Method I or Method II. Method I is usually suitable but in certain cases, the dye used in the dressing may interfere with the normal blue colour of the chloroform layer in the titration. In these circumstances, Method II may be used.

Method I

Dry 5 g (*w g*) of the impregnated pad, in small pieces, to constant weight at 105°C. Immerse the dried material in 100 ml of 1 M methanolic hydrochloric

acid prepared using gaseous hydrogen chloride, shake for 30 min, decant the solution, transfer 50 ml to a round flat-bottomed flask, evaporate to 5 to 10 ml on a water bath and allow to cool. Add 40 ml of water and 0.2 ml of bromophenol blue solution, titrate with 2 M sodium hydroxide *VS* to a blue or green colour and add 5 ml in excess. Add 3.0 g of anhydrous sodium acetate and 10 ml of chloroform, shake and titrate with a 0.014 percent (*m/v*) solution of sodium dodecyl sulphate until the chloroform layer changes to colourless or yellow (V_1 ml). Repeat the procedure using, in place of the material being examined, 5 g of undyed non-impregnated base fabric, on which 5.0 ml of a 0.140 percent (*m/v*) solution of domiphen bromide in methanol has been dispersed and which has been subsequently dried at 105°C (V_2 ml).

Calculate the percentage of $C_{22}H_{40}BrNO$ in the sample from the expression $0.7 V_1/wV_2$.

Method II

Prepare a chromatographic column in the following manner. Suspend a suitable quantity of strongly basic anion exchange resin (Amberlite IRA-400, Deacidite FF-IP and Zerolite FF are suitable) in 2 M hydrochloric acid and allow to stand for 10 min. Transfer sufficient of the suspension to a suitable chromatographic tube, fitted with a glass wool plug at its tapered end, to give a column height of about 15 cm, wash the column with water until the eluate has a pH of 6 to 7 and then wash with several volumes of methanol.

Dry 5 g of the material being examined, in small pieces, to constant weight at 105°C, immerse in 100 ml of methanol in a 250-ml conical flask and shake for 30 min. Decant the supernatant liquid, transfer 50 ml to a separating funnel arranged so that the solution flows through the prepared column at a rate of about 3 ml/min, collect the eluate in a flat-bottomed flask, wash the column with 40 ml of methanol, evaporate the combined eluate and washings on a water bath to a volume of 5 to 10 ml, allow to cool and proceed as described under Method I, beginning at the words 'Add 40 ml of water and'.

6.15.7 Merbromin NF

6.15.7.1 Standard preparation

Dissolve about 1.0 g of accurately weighed merbromin NF standard sample in 100 ml of 0.25 percent ammonium acetate solution in volumetric flask. Pipette 1 ml of above solution and dilute to 100 ml with ammonium acetate solution in standard volumetric flask. Pipette 10 ml of the above solution and dilute to 100 ml with ammonium acetate solution in standard volumetric flask. Pipette 10 ml of the above solution and dilute to 100 ml with ammonium acetate

solution in standard volumetric flask.

6.15.7.2 Sample preparation

Peel off sufficient medicated pads from adhesive dressing. Weigh accurately about 1 g of the pads and extract medication thrice in 50 ml boiling ammonium acetate solution each time. Extract the pads in one more 50 ml boiling ammonium acetate solution each time. Extract the containing about 0.2 ml of strong ammonia solution containing 27 to 30 percent ammonia. The pads should become almost colourless. Combine the extract and dilute to 250 ml with ammonium acetate solution. Centrifuge this solution for 30 min at 1 600 rpm to remove suspended fibres. Pipette 25 ml of the clear supernatant solution and dilute to 100 ml with ammonium acetate.

Measure the absorption of standard dilution and sample dilution against ammonium acetate as blank at 520 nm.

6.15.7.3 Calculation

$$\text{Merbromin (percent)} = \frac{A \times W_1}{S \times W_2}$$

where

S = standard reading,

A = sample reading,

W_1 = weight of standard, and

W_2 = weight of sample.

6.16 Content of Zinc Oxide in the Adhesive Mass

Heat 1 g of the material being examined, cut into strips, with 75 ml of chloroform, 6 ml of 6 M acetic acid and 40 ml of water in a conical flask until the chloroform layer boils, continue heating for 4 min, swirling the mixture frequently, allow to cool slightly, stopper the flask, shake vigorously for 2 min, rinse the stopper with water and collect the rinsings in the flask. Add 10 ml of ammonia buffer pH 10.9 and, while still warm, titrate with 0.1 M disodium edetate *VS*, with continuous swirling, using as indicator 0.2 ml of a solution containing 0.5 percent (*m/v*) of mordant black II and 4.5 percent (*m/v*) of hydroxylamine hydrochloride in methanol. Each ml of 0.1 M disodium edetate *VS* is equivalent to 0.008 137 g of zinc oxide (ZnO). Decant the titrated liquid through a sieve with a nominal mesh aperture of 106 μm , return any collected fibres to the fabric in the flask, wash the material with several successive small quantities of chloroform and dry at 105°C. Allow the dried material to equilibrate with the atmosphere and weigh. The weight of the adhesive mass is given by the difference in weights. Calculate the percentage content of ZnO in the adhesive mass.

6.17 X-Ray Opacity

Place the material being examined or a representative sample of the X-ray detectable component under a 30-mm thickness of 99 percent pure aluminium of commerce, in the centre of a non-screen X-ray film positioned on a sheet of lead not less than 2 mm thick, or on an equivalent thickness of lead rubber sheet, masking any parts of the film not covered by the test piece with 2 mm of lead, or an equivalent thickness of lead-rubber sheet, to prevent scattered radiation from affecting the film. Irradiate the specimen and the aluminium simultaneously with X-rays at 70 kV peak, using an exposure sufficient to give a logarithmic photographic density of about 1.0 through a 10-mm thickness of the aluminium. When the developed radiograph is examined by transmitted light, the specimen image is clearly visible as a lighter area against a darker background.

6.18 Sulphated Ash of Surgical Dressings

Introduce 5 g into a previously heated and cooled, tared crucible, heat cautiously over a naked flame and then carefully to 600°C and allow to cool. Add a few drops of 1 M sulphuric acid, heat and incinerate until all the black particles have disappeared and allow to cool. Add a few drops of 2 M ammonium carbonate, carefully evaporate and incinerate, allow to cool and weigh again. Incinerate for 5 min and allow to cool; repeat until two successive weighings do not differ by more than 0.5 mg.

6.19 Water Retention Capacity

6.19.1 Apparatus

6.19.2 Stainless Steel Tank

6.19.3 Stainless Steel Tray

The tray has a perforated metal base which can be suspended in the stainless steel tank, permitting a moistened material aid upon its surface to drain freely through the perforations. The base is perforated with circular holes, 3 mm in diameter, evenly spaced, so that the centre of each hole is 5 mm from the centres of those adjoining it.

6.19.4 Metal Weight

Use a suitable non-corrodible material which exerts a pressure of 2 kN m^{-2} (20 gf cm^{-2}).

6.20 Method

Weigh the material being examined and place it on the perforated metal tray with the surface intended for wound contact in direct contact with the perforated surface.

Immerse the tray and material in water at a temperature of 20°C for 10 s. Transfer the tray and material to the stainless steel tank and allow the contents to drain for 10 s. Place the metal weight on the surface of the material such that a force of 2 kN m^{-2} is applied evenly over the surface of the sample, leave for 30 s and then remove it carefully. Transfer the material immediately by means of a pair of tweezers to a tared dish, taking care not to lose any water in the process; weigh and calculate the equivalent water-retention capacity for an area of 100 cm^2 of the dressing fabric. Record the results of five determinations and calculate the average water retention capacity.

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This Indian Standard has been developed from Doc : No. MHD 15 (2542).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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